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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,456	11/14/2001	Maurice Zauderer	1821.0070004/EKS/EJH/TAC	6770

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EXAMINER
EPPERSON, JON D

ART UNIT	PAPER NUMBER
1639	9

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/987,456	ZAUDERER ET AL.	
	Examiner	Art Unit	
	Jon D Epperson	1639	

-- Th MAILING DATE of this communication appears on the cover sheet with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-83 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-83 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-49, 52-79 and 83 drawn to a method for "screening" a library by "selecting polynucleotides which encode an antigen-specific immunoglobulin molecule", classified variously in class 435, subclass 7.1, 7.2, DIG 6.

   II. Claims 50-51 drawn to a method for "producing" a library, classified variously in class 435, subclass 6, DIG 47.

   III. Claim 80, drawn to a kit, classified variously in class 436, subclass 808; class 435, subclass 975.

   IV. Claim 81, drawn to an antibody, classified in class 530, subclass 387.1+.

   V. Claim 82, drawn to a composition, classified variously in class 424, subclass 464+, class 424, subclass 130.1+

2. The inventions are distinct, each from the other because of the following reasons:

3. Groups I-V represent separate and patentably distinct inventions. Groups I-II are drawn to different methods and Groups III-V are drawn to different products and/or kits (i.e., e.g., which are directed to different purposes, use different materials, recite different method or

process steps for the preparation of different product(s), screening of different characteristics, such as different binding affinities, different biochemical reaction conditions, etc. or lead to different final results). Therefore, the groups that describe these products and methods have different issues regarding patentability and enablement, and represent patentably distinct subject matter, which merits separate and burdensome searches. Art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing

4. Groups I and II represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. In this case, the method of Group II employs is drawn to a method of "producing" a library of polynucleotides using a virus vector, whereas Group I is drawn to a method of "screening" an expression library. As a result, Group I requires a different reagent (e.g., polypeptides) that are not required by Group I. In addition, since Group II does not require an antigen and, as a result, the Groups will produce different results i.e., peptide screening versus nucleic acid production. Therefore, Groups I and II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

5. Likewise, Groups IV and V represent patentably distinct products. Groups IV and V represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group V requires "a pharmaceutically acceptable carrier", which is not required by Group IV.

Furthermore, Group IV can be used for different purposes than Group V e.g., screening methods. Therefore, art anticipating or rendering obvious each of the above-identified groups respectively would not necessarily anticipate or render obvious another group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups IV and V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

6. In addition, Groups III and IV-V represent separate and distinct products. They differ in respect to their properties, their use and the synthetic methodology for making them. In the instant case, Group III refers to a plurality of articles grouped together to form a "kit", whereas Groups IV-V refers to only a single article or an article with a pharmaceutically acceptable carrier. These Groups also have different purposes e.g., the kit can be used for screening whereas the pharmaceutical composition is used for treating health problems. Therefore, Groups III and IV-V have different issues regarding patentability and enablement and represent patentably distinct subject matter.

7. Finally, if the applicant argues that Groups I and IV are somehow related as process of making and product made, the inventions can be considered to be distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different products or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, (2) the product as claimed can be

made by another materially different process e.g., transgenic mice, bacteriophage display, virus without tri-molecular recombination, solid-phase synthesis, computer design.

8. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

Species Election

9. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

10. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of host cells (e.g., see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of host cells e.g., COS cells. Please also indicate whether the elected host cells are permissive for the production of infectious viral particles (e.g., see claim 39).

Subgroup 2: Species of immunoglobulin source (e.g., see claims 1, 9)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source e.g., human.

Subgroup 3: Species of immunoglobulin (see claims 1, 10 -15)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source e.g., heterologous naturally occurring membrane heavy chain fusion protein that contains a fas death domain. Please indicate whether it is "naturally" occurring and whether or not it is "membrane" bound and whether or not it is a "fusion" protein and whether or not it contains a "heterologous" transmembrane domain and whether of not it contains a "fas death" domain.

Subgroup 4: Species of immunolgobulin type (e.g., see claims 1, 16, 19)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source e.g., IgM heavy chain.

Subgroup 5: Species of first and second library construction (e.g., see claims 1, 22, 25)

Applicant must elect, for the purposes of search, a ***single species*** of first library construction and second library construction e.g., eukaryotic virus vector, plasmid. Please specify the actual virus or plasmid used (e.g., vaccinia virus vector, see claims 36-37). Please also indicate whether it is an "animal" virus (see claim 29. Please also indicate whether it is capable of producing infectious viral particles in mammalian cells (e.g., claim 30). Please also indicate the type of genome e.g., linear, double-stranded DNA (e.g., see claim 33). Please also indicate whether the virus is attenuated (e.g., see claim 40). Please also indicate whether the virus is deficient in D4R synthesis (e.g., see claim 41).

Subgroup 6: Species of promoter (e.g., see claims 46-47)

Applicant must elect, for the purposes of search, a ***single species*** of promoter e.g., vaccinia virus p7.5 promoter. Please also indicate whether the promoter is a synthetic early/late promoter and whether the promoter is constitutive (e.g., see claims 45, 47).

Subgroup 7: Species of detection (e.g., see claim 53)

Applicant must elect, for the purposes of search, a ***single species*** of detection e.g., antigen-induced cell death, antigen-induced signaling. Please also indicate whether the host cells respond to "cross-linking" of antigen-specific immunoglobulin receptors (e.g., see claim 56). Please also indicate whether a reporter molecule is used and specify the type of reporter e.g., green fluorescent protein (e.g., see claim 62).

Subgroup 8: Species of antigen attachment (e.g., see claims 68-80)

Applicant must elect, for the purposes of search, a ***single species*** of antigen attachment e.g., magnetic bead, antigen presenting cell, fluorescent tag. If Applicants selects antigen

presenting cell, Applicant must further elect whether or not it is presented in an antigen-free presenting cell and if so indicate the type e.g., L cell, Cos7 cell (see claim 70).

11. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 50 is generic.

Subgroup 1: Species host cell (e.g., see claims 50, 51)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., COS.

Subgroup 2: Species of eukaryotic virus vector (e.g., see claims 50, 51)

Applicant must elect, for the purposes of search, a ***single species*** of eukaryotic virus vector Please specify the actual virus used (e.g., vaccinia virus vector, see claims 36-37). Please also indicate whether it is an "animal" virus (see claim 29. Please also indicate whether it is capable of producing infectious viral particles in mammalian cells (e.g., claim 30). Please also indicate the type of genome e.g., linear, double-stranded DNA (e.g., see claim 33). Please also indicate whether the virus is attenuated (e.g., see claim 40). Please also indicate whether the virus is deficient in D4R synthesis (e.g., see claim 41).

Subgroup 3: Species of transfer plasmids (e.g., see claims 50, 51)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., specify type including whether or not it has a vaccina promoter and also any relevant non essetial virus sequences e.g., poxvirus.

Subgroup 4: Species of immunoglobulin source (e.g., see claims 1, 9)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source e.g., human.

Subgroup 5: Species of immunoglobulin (see claims 1, 10 -15)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source e.g., heterologous naturally occurring membrane heavy chain fusion protein that contains a fas death domain. Please indicate whether it is "naturally" occurring and whether or not it is "membrane" bound and whether or not it is a "fusion" protein and

whether or not it contains a "heterologous" transmembrane domain and whether of not it contains a "fas death" domain.

Subgroup 6: Species of immunolgobulin type (e.g., see claims 1, 16, 19)

Applicant must elect, for the purposes of search, a ***single species*** of immunoglobulin source e.g., IgM heavy chain.

12. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 80 is generic.

Subgroup 1: Species host cell (e.g., see claims 80)

Applicant must elect, for the purposes of search, a ***single species*** of host cell e.g., COS.

Subgroup 2: Species first library (e.g., see claims 80)

Applicant must elect, for the purposes of search, a ***single species*** of first library.

Subgroup 3: Species first immunoglobulin subunit (e.g., see claims 80)

Applicant must elect, for the purposes of search, a ***single species*** of first immunoglobulin subunit.

Subgroup 4: Species signal peptide (e.g., see claims 80)

Applicant must elect, for the purposes of search, a ***single species*** of signal peptide.

Subgroup 5: Species virus particles (e.g., see claims 80)

Applicant must elect, for the purposes of search, a ***single species*** of virus particles.

13. If applicant elects the invention of Group IV-V, applicant is required to elect from the following patentably distinct species. Claims 81 and 82 are generic for Groups IV and V, respectively.

Subgroup 1: Species antibody (e.g., see claim 81)

Applicant must elect, for the purposes of search, a ***single species*** of antibody i.e., provide Sequence ID NO to which Applicant will be restricted to as a group. Please note that each antibody constitutes its own group and is not a "species election" for purposes of search.

Subgroup 2: Species of carrier (e.g., see claim 82)

If Applicant elects Group V, Applicant must further elect a ***single species*** of carrier.

14. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 18 and 19 below).

15. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

17. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

18. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

20. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

21. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

22. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
September 7, 2003

BENNETT CELSA
PRIMARY EXAMINER